SHIPPED: 1-20-58, from Los Angeles, Calif., by Takara Laboratories Corp.

LABEL IN PART: "Takara Douche Powder * * * Alum, Oil Peppermint, Boric Acid, Phenol * * * For a Douche: Dissolve one teaspoonful of Takara to each quart of comfortably warm water. Use as desired."

LIBELED: 2-14-58, W. Dist. Wash.

CHARGE: 502(f)(2)—the labeling of the article, when shipped, failed to bear such adequate warnings against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since its labeling failed to warn that the article should not be used more than twice weekly, unless otherwise directed by a physician.

DISPOSITION: 7-9-58. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

5651. Pentosol. (F.D.C. No. 40611. S. Nos. 25-669 M, 66-340 M, 74-129 M.)

INFORMATION FILED: 3-24-58, N. Dist. Calif., against Invenex Pharmaceuticals, a corporation, San Francisco, Calif., and Jack R. Baker, president.

ALLEGED VIOLATION: On 6-10-57, the defendants gave to a firm engaged in the business of shipping drugs in interstate commerce, including *Pentosol* supplied by the defendants, an invoice containing a guaranty that the *Pentosol* listed in the invoice was neither adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On 6-10-57, the defendants sold, invoiced, and delivered, a quantity of *Pentosol* to the holder of the guaranty at Oakland, Calif.

LABEL IN PART: (Vial) "Pentosol 100cc Multiple Dose Vial Sterile Solution Each cc Contains: Pentobarbital Sodium 1 gr Benzyl Alcohol 2% Water for Injection qs."

CHARGE: 501(c)—the strength of the article differed from that which it purported and was represented to possess, namely, 1 grain of pentobarbital sodium in each cubic centimeter; and 502(a)—the label statement "Each cc Contains: Pentobarbital Sodium 1 gr." was false and misleading since each cubic centimeter of the article contained less than 1 gr. of pentobarbital sodium.

PLEA: Nolo contendere.

DISPOSITION: 8-12-58. Corporation—fined $200; individual—fined $50.

5652. Sodium nitrite and phenobarbital tablets. (F.D.C. No. 41435. S. No. 14-761 P.)

QUANTITY: 3 500-tablet pkgs., 8 100-tablet pkgs., and 21 2,500-tablet pkgs., at Muncie, Ind.

SHIPPED: 10-18-57, from Cincinnati, Ohio.

RESULTS OF INVESTIGATION: Examination showed the article to be a green-colored tablet containing about 0.23 grain of phenobarbital per tablet, or approximately the declared amount, and about 1.38 grains of sodium nitrite per tablet, or about 69 percent of the declared amount.

The article had been repackaged by the consignee from bulk stock shipped as described above.

LIBELED: 3-6-58, S. Dist. Ind.

*See also Nos. 5641, 5642.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, 2 grains of sodium nitrite per tablet; and 502(a)—the label statement "Each tablet contains Sodium Nitrite 2 gr." was false and misleading.

DISPOSITION: 6-30-58. Default—destruction.

5653. Beta Foplex capsules. (F.D.C. No. 41423. S. No. 90-286 M.)

QUANTITY: 1 drum containing 13,850 capsules, and 15 ctns., each containing 12 btls. of 42 capsules each, at Stamford, Conn.

SHIPPED: 3-30-56, from Long Island City, N.Y.

RESULTS OF INVESTIGATION: The capsules in the bottles were repackaged from the bulk drum by the consignee.

LIBELED: 2-24-58, Dist. Conn.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 1 milligram of thiamine hydrochloride (vitamin B_1) per capsule; and 502(a)—the label statement "Each capsule contains: * * * Thiamine Hydrochloride * * * 1 mg." was false and misleading as applied to a product which contained less than the declared amount of vitamin B_1 per capsule.

DISPOSITION: 7-12-58. Default—delivered for the use of charitable organizations.

5654. Rubber prophylactics. (F.D.C. No. 41615. S. No. 25-010 P.)

QUANTITY: 248 ctns., each containing ½ gross, at Minneapolis, Minn.

SHIPPED: 9-12-57 and 12-31-57, from Akron, Ohio, by the Killashun Sales Div. of the Akwell Corp.

LABEL IN PART: (Pkg.) "One Sultan Lubricated Prophylactic."

RESULTS OF INVESTIGATION: Examination of 166 *prophylactics* showed that 1.9 percent were defective in that they contained holes.

LIBELED: 3-11-58, Dist. Minn.

CHARGE: 501(c)—the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: 5-21-58. Default—destruction.

5655. Rubber prophylactics. (F.D.C. No. 41479. S. No. 14-370 P.)

QUANTITY: 516 gross at Chicago, Ill.

SHIPPED: 12-20-57, from Akron, Ohio, by Killashun Sales Div. of the Akwell Corp.

LABEL IN PART: "Cello's Prophylactics Latex."

RESULTS OF INVESTIGATION: Examination of 212 *prophylactics* showed three to be defective in that two contained holes and one was excessively fragile.

LIBELED: 3-20-58, N. Dist. Ill.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported to possess; and 502(a)—the label statement "Prophylactics" was false and misleading as applied to an article that was excessively fragile and contained holes.

DISPOSITION: 5-28-58. Default—destruction.